DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 1-31 & 44-46 in the reply filed on 11/06/2009 is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 4, 10-11, 14-21, 22-25, 31 & 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Pitt (WO00/53795).

Pitt teaches a method of preparing a stem cell by taking a lipoaspirate sample, treating the sample with collagenase and centrifuging the sample multiple times (including at 260g) to separate the cells from other cells including erythrocytes. The reference anticipates the claim subject matter.

Claims 1- 13, 14-21, 22-25, 27, 31 & 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Artecell (WO01/62901)

Atrcell teaches a method of preparing a stem cell by taking a lipoaspirate sample and centrifuging the sample using a density gradient medium Ficoll or Percoll) to separate the cells from other cells including erythrocytes. The reference anticipates the claim subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 & 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piit and Artecell (as cited above).

Pitt teaches a method of preparing a stem cell by taking a lipoaspirate sample, treating the sample with collagenase and centrifuging the sample multiple times (including at 260g) to separate the cells from other cells including erythrocytes.

Atrcell teaches a method of preparing a stem cell by taking a lipoaspirate sample and centrifuging the sample using a density gradient medium Ficoll or Percoll) to separate the cells from other cells including erythrocytes. The reference anticipates the claim subject matter.

The references do not teach every claimed embodiment of applicant's invention however the references clearly teach that the desired cells can be isolated from a lipoaspirate wherein the cells are them separated from "contaminants" such as extracellular matrix, erythrocytes, etc by known methods such as centrifugation and density gradient centrifugation and proteolytic treatment.

Applicant is directed to pages 12-13 of *KSR v Teleflex* (500 US 398 2007) " … the Court has held that a "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what is already known into the field of its monopoly and diminishes the resources available to skillful men." Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp., 340 U. S. 147, 152 (1950). This is a principal reason for declining to allow patents for what is obvious. The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either ***in the same field or a different one(emphasis added)***. If a person of ordinary

skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Clearly in the instant case the art recognizes where to collect the desired cells, what "undesired elements" are in the collected and which techniques can be used to isolate the desired cells based on their well known physical and biochemical characteristics using notoriously old and well known techniques.

Regarding the specific centrifugation speeds used, density gradients or reagent concentrations: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) ; see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.");< ** In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493

U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Applicant would appear to allege criticality with regard to the specific concentrations, speeds, etc of the process. However, there is not clear and convincing evidence of criticality now of record. Any slight difference in results described in the specification would appear to be no more than a difference of degree rather than a difference in kind. This type of evidence is insufficient to overcome a prima facie case of obviousness. Slight variations in results are expected in microbiological/biochemical processes such as described herein. The differences noted do not rise to the level of unexpected or unobvious. Therefore the data is insufficient to preclude the instant rejection.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon B. Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Fri 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651